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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,869	12/21/2001	James Samsoondar	213202.00354	4454

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EXAMINER	
WALLENHORST, MAUREEN	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 02/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,869	SAMSOONDAR, JAMES	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *67,69-83 and 96* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *67,69-83 and 96* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/147,373.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. Applicant's election with traverse of Group III in the response received on November 26, 2003 is acknowledged. The traversal is on the ground(s) that a search of the art for one group will necessarily include a search of the art for the other groups of claims. This is not found persuasive because the search for Groups I and II does not require looking for the quality control material of Group III, having an indicator of hemolysis, a simulator of turbidity, bilirubin, etc, since Groups I and II do not even recite such a quality control material.

The requirement is still deemed proper and is therefore made FINAL.

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: It fails to claim priority to PCT application serial no. PCT/CA97/00418 under 35 USC 119.

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 250 words. It is important that the abstract not exceed 250 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

4. The abstract of the disclosure is objected to because of the inclusion of legal phraseology such as “comprises” and “comprising”. In addition, the abstract is too long (i.e. greater than 150 words). Correction is required. See MPEP § 608.01(b).

5. The disclosure is objected to because of the following informalities: On page 1 of the specification in the first sentence (continuation information), the phrase --, and now US Patent no. 6,372,503—should be inserted after the phrase "US Serial no. 09/147,373, filed June 12, 1998" so as to update the status of the parent application.

Appropriate correction is required.

6. Claims 67, 69-70, 75-76 and 96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On line 4 of claim 67, the phrase "wherein one or more analytes is" is indefinite since it seems that the components being recited after this phrase are the substances contained in the quality control material, not the analytes being mimicked. Therefore, it is suggested to change this phrase to –wherein said one or more substances are--.

Claim 69 is indefinite since it depends on canceled claim 68.

In claim 75, both oxy-Hb and cyanmet-Hb are recited twice as the one or more substances in the quality control material.

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 67, 69-71, 73, 75, 77, 79 and 80 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-4 and 10-12 of U.S. Patent No. 6,372,503. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite a quality control material comprising one or more substances that mimic one or more of an indicator of hemolysis, bilirubin, turbidity and biliverdin. Both sets of claims recite that the indicator of hemolysis can be total hemoglobin, amaranth, phenol red or basic fushsin. While the claims of US Patent no. 6,372,503 do not recite that the quality control material is exposed to atmospheric conditions, such a limitation would have been obvious to one of ordinary skill in the art since the quality control material taught in US Patent no. 6,372,503 is not recited as being stored in a closed container under a particular gaseous atmosphere.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 67, 69-83 and 96 are rejected under 35 U.S.C. 102(b) as being anticipated by Campbell et al (EP 132,399, submitted in the Information Disclosure Statement filed on May 30, 2002).

Campbell et al teach of a cooximetry quality control reagent, which comprises a solution of one or more dyes, which solution mimics the spectral response of whole blood at a plurality of wavelengths in the visible region of the spectrum. The dyes serve to mimic several hemoglobin species found in blood including total hemoglobin, oxyhemoglobin and methemoglobin. One of the dyes can be amaranth. See lines 1-8 on page 9 of Campbell et al. The quality control material contains no bilirubin, and it is exposed to atmospheric conditions since Campbell et al teach of preparing the solution in an open container and then analyzing the solution with a cooximeter. Since claims 67, 69-83 and 96 only require at least one substance, one of which mimics and indicator of hemolysis such as total Hb, the teaching of Campbell et al anticipates these claims.

11. Claims 67 and 79-80 are rejected under 35 U.S.C. 102(b) as being anticipated by Grandjean (US Patent no. 5,278,073, submitted in the Information Disclosure Statement filed on May 27, 2003).

Grandjean teaches of a calibration standard solution to be used in bilirubin assays, which comprises a material such as methyl orange to mimic the absorption spectrum of bilirubin. See lines 52-61 in column 4 of Grandjean. Since claims 67 and 79-80 only require at least one substance, one of which mimics bilirubin, the teaching of Grandjean anticipates these claims.

12. Claims 67 and 79-80 are rejected under 35 U.S.C. 102(b) as being anticipated by Artiss et al (US Patent no 5,310,679, submitted in the Information Disclosure Statement filed on May 27, 2003).

Artiss et al teach of a bilirubin standard solution containing bilirubin and Intralipid at a concentration of 12 g/L to mimic turbidity in a biological sample. See lines 34-43 in column 6

of Artiss et al. Since claims 67 and 79-80 only require at least one substance, one of which mimics turbidity, the teaching of Artiss et al anticipates these claims.

13. Claims 67, 75-78 and 80-81 are rejected under 35 U.S.C. 102(b) as being anticipated by Sorensen et al (US Patent no. 4,116,336, submitted in the Information Disclosure Statement filed on May 30, 2002).

Sorensen et al teach of a reference liquid for the calibration and/or quality control of blood gas analyzers, which also include a measurement of total hemoglobin. The reference liquid has parameters that are known with respect to pH, pCO2, pO2 and if desired, total hemoglobin. When the reference liquid contains a material to simulate or mimic total hemoglobin and thus permit the use of the reference liquid for quality control and calibration of the hemoglobin measuring part of a blood measuring instrument, the reference liquid contains a coloring component or dye to mimic total hemoglobin. Sorensen et al teach that the dye is preferably amaranth because of its stability. See lines 24-52 in column 5 of Sorensen et al. Therefore, Sorensen et al teach of a quality control material, which comprises a substance that mimics an indicator of hemolysis, i.e. total hemoglobin, and wherein the indicator of hemolysis is a single substance of amaranth. See examples 4 and 5 in Sorensen et al, which teach that amaranth is the only dye in the reference liquid for simulating total hemoglobin. The reference liquid taught by Sorensen et al also does not contain bilirubin. Since claims 67, 75-78 and 80-81 only require at least one substance, one of which mimics total hemoglobin, the teaching of Sorensen et al anticipates these claims.

14. Claims 67, 69-81 and 96 are rejected under 35 U.S.C. 102(b) as being anticipated by either patent to Jacobs et al (either US Patent no. 5,846,492, submitted in the Information Disclosure Statement filed on May 30, 2002 or US Patent no. 6,013,528).

Both patents to Jacobs et al teach of calibrator liquids for spectrophotometric analysis, which contain known amounts of hemoglobin, Intralipid and biliverdin in a human serum matrix. Intralipid serves to mimic turbidity in a blood sample. See lines 26-35 in column 8 and table 1 in Jacobs et al ('528), and lines 48-56 in column 8 and table 1 in Jacobs et al ('492). In this embodiment, there is no bilirubin present in the calibrator solutions. In a second embodiment taught by both patents to Jacobs et al, there is bilirubin present in the calibrator solutions. See lines 32-60 in column 10 of the '492 patent, and lines 10-38 in column 10 of the '528 patent. The calibrator solutions are exposed to atmospheric conditions since Jacobs et al teach that the solutions are prepared in an open sample vessel, and then aspirated by a probe into an analyzer. Since the instant claims recite new matter (i.e. a perfluorocarbon-like blood substitute, a hemoglobin-based blood substitute, exposure to atmospheric conditions, etc) that is not present in the parent application (serial no. 09/147,373), the effective filing date of the instant application is December 21, 2001. Therefore, both patents to Jacobs et al qualify as prior art under 35 USC 102(b).

15. Claims 67, 69-81 and 96 are rejected under 35 U.S.C. 102(e) as being anticipated by Jacobs et al (US 2003/0068822, submitted in the Information Disclosure Statement filed on June 9, 2003).

Jacobs et al teach of a control solution for a hemoglobin assay, which comprises an indicator of hemolysis. The indicator is a cross-linked blood substitute, preferably one known

under the tradename OXYGLOBIN. This blood substitute product has similar spectrophotometric characteristics as hemoglobin-containing fractions of hemolysed blood. There is no bilirubin in the control solution, and the solution is exposed to atmospheric conditions since Jacobs et al teach that it is prepared in an open sample vessel, and then measured by an analyzer. Since the instant claims recite new matter (i.e. a perfluorocarbon-like blood substitute, a hemoglobin-based blood substitute, exposure to atmospheric conditions, etc) that is not present in the parent application (serial no. 09/147,373), the effective filing date of the instant application is December 21, 2001. Therefore, the publication to Jacobs et al qualifies as prior art under 35 USC 102(e).

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

January 24, 2004

Maureen M. Wallenhorst
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PRIMARY EXAMINER
GROUP [redacted] 1700